

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTSIn re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-a-Care of
the Florida Keys, Inc. v. Abbott Laboratories,
Inc.*, Civil Action No. 07-11618-PBSMDL No. 1456
Master File No. 01-12257-PBS
Subcategory Case No. 07-11618 -PBS

Hon. Patti B. Saris

Magistrate Judge Marianne B. Bowler

**PLAINTIFF VEN-A-CARE'S OPPOSITION TO ABBOTT LABORATORIES'
MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS PROFFERED BY
PLAINTIFF'S EXPERT MARK G. DUGGAN, PH.D.**

Abbott PPD priced its Ery drugs in a very unique manner; it hid actual wholesale invoice prices, wholesale costs, and actual pharmacy prices while causing inflated, false WAC prices, as well as resulting inflated Direct and AWP prices, to be published. Dr. Duggan's analysis clearly shows these published prices exceeded, on average, usual transaction prices significantly; from more than 60% to over 400%. (See Ven-A-Care's Statement of Fact in Support of Motion for Partial Summary Judgment filed 08/28/09, Document No. 399 hereinafter referred to as VAC SOF in Support of VAC MPSJ) (VAC SOF in Support of VAC MPSJ ¶¶52 through ¶¶54).¹ Abbott further published and caused First Data Bank and Redbook to publish these same fake WAC, AWP and Direct prices. *Id.* at ¶ 14; see also VAC SOF in Support of VAC MPSJ ¶¶134 - 136 - Parker dep. trans. 55:20-56:16; 85:3-8; 104:10-105:1; 106:3-11; and Gerzel dep. trans. 65:4-66:24; 70:1-74:5). These prices were utilized by state Medicaid agencies to calculate drug reimbursement amounts. (See VAC SOF in Support of VAC MPSJ ¶ 60). Abbott now tries to strike the testimony of a prominent healthcare economist, Dr. Mark Duggan, in an effort to avoid

¹ The most highly utilized Ery product had spreads that ranged, on average, over 300% above average pharmacy transaction prices. (See Expert Report of Dr. Duggan ("Ery") at p. 7).

the repercussions of its conduct. The qualifications of Dr. Duggan are impressive. He holds a Ph.D. in Economics from Harvard, undergraduate and graduate degrees in Electrical Engineering from M.I.T. and has received numerous renowned awards in the field of economics.² (See Declaration of Dr. Duggan ¶ 1-4). While Abbott oddly criticizes Dr. Duggan for not having opined in litigation often, Abbott fails to mention that Dr. Duggan has produced extensive healthcare research which has been published in prominent, peer-reviewed economic journals. (See Expert Report of Dr. Duggan pp. 3-7; see also Declaration of Dr. Duggan ¶ 4-9). Importantly, in these past widely-accepted research efforts Dr. Duggan utilized methodologies and techniques such as those employed instantly. (Expert Report of Dr. Duggan p. 6). Abbott's desperate Motion to Strike urges two key arguments; both of which are wrong-headed.

First, Abbott claims Dr. Duggan did not determine how Abbott's pricing conduct caused Medicaid reimbursements. Yet, Dr. Duggan clearly set forth in his report, and in his testimony, that Abbott's concealment of pricing and publication of fake pricing resulted in Medicaid payments. (See Expert Report of Dr. Duggan at p. 2). These Ery drug payments are significant; over \$26,000,000.00, of which \$15,559,000.00 was federal dollars. (Declaration of Dr. Duggan ¶ 33). The connection between the payments and Abbott's conduct is distinct. While Abbott wishes to conveniently ignore this fact, the truth is otherwise.

Second, Abbott takes issue with Dr. Duggan's extrapolation methods for a minority of the Medicaid claims at issue. This approach selectively turns a blind-eye to the fact that approximately 70% of all actual Medicaid claims for the Ery drugs were precisely re-adjudicated using Abbott's hidden transaction pricing in connection with this exacting Medicaid claims-level data. (See Duggan dep. trans. at 101:1 – 102:13). Therefore, ultimately Abbott must restrict its complaint to extrapolations Dr. Duggan reached regarding the remaining minority of the Medicaid claims reflected in more summary-level data. Dr. Duggan used the actual claims-level data produced by the respective state Medicaid programs to form extrapolations to the other sets of actual Medicaid claims data. While Dr. Duggan meticulously described his approach for

² In addition to being a tenured professor at the University of Maryland, Dr. Duggan is currently serving as Senior Economist for Health Care on President Obama's Council of Economic Advisors.

extrapolating and comparing the actual state claims data to the other Medicaid data, Abbott misconstrues and contorts Dr. Duggan's analysis. Abbott do so because Dr. Duggan clearly explains how his extrapolations were reasonable, accepted within the field of healthcare economics, and conservative. (See Expert Report of Duggan at ¶ 5; see also Duggan dep. trans. at 190:19 – 194:7; see also Declaration of Dr. Duggan ¶¶ 38-66).

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INTRODUCTION

Ven-a-Care retained Dr. Mark Duggan, Ph.D., to calculate a reasonable estimate of damages.³ Dr. Duggan is a Harvard-trained economist currently taking a one-year sabbatical from his tenured university position to be the Senior Economist for Health Care on President Obama's Council of Economic Advisors. Dr. Duggan has substantial experience applying econometric principles to empirical studies of nationwide Medicaid spending. Dr. Duggan's extensive healthcare research and analysis has been subjected to peer-review and has been published in top economic journals. (See Duggan report at pp. 3-7). This experience in non-litigation contexts provided Dr. Duggan with the skill set and analysis techniques he brought to bear in this case. (See Expert Report of Dr. Duggan at p. 5-7; see also Duggan dep. trans. at 101:1-102:13). These techniques are standard within the field of healthcare economics and have been utilized and accepted by Dr. Duggan and other leading healthcare economists. (See Expert Report of Dr. Duggan report at p. 2; see also Declaration of Dr. Duggan ¶ 63).

Abbott complains Dr. Duggan has ignored the impact of ceiling prices such as FUL and MAC. This is a complete misstatement. Dr. Duggan very carefully considered maximum reimbursement limits and only calculated differences in reimbursement when "lesser of" formulas were in place which create a very clear connection between Abbott's pricing conduct and the reimbursements that would have been paid. (See Expert Report of Dr. Duggan at pp. 27, 41, 47, 50, 58, 62, 65, 69, 72, 76, 80, 83, 86; see also Duggan dep. trans. at pp. 94:3-95:13; 97:1-98:11). This approach is entirely consistent with this Court's rulings in which it held that if a drug company "had reported a true AWP for its branded multi-source drugs, Medicare would have reimbursed based on that branded drug's AWP, rather than the inflated median." In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F.Supp.2d 20, 6-21-2007 (D.

³ The United States and Ven-a-Care also retained Dr. Duggan in the other action pending against Abbott in which the government intervened. Abbott raises basically the same issues in both cases regarding Dr. Duggan. Accordingly, Ven-a-Care incorporates by references the briefing and supporting evidence presented in that matter by the United States and Ven-a-Care in support of Dr. Duggan.

Mass. 2007). This same legal reasoning applies to virtually every state Medicaid reimbursement system where MACs and FULs were compared to NDC-specific reimbursement calculations known as estimated acquisition costs (“EACs”) and payment was made based on the lower amount. Abbott’s concealed transaction prices would have resulted in lower EACs and hence lower reimbursements in every instance of difference calculated by Dr. Duggan. Abbott’s reliance upon this Court’s ruling regarding California Medicaid’s use of state-specific ceiling prices is inappropriate because California did not normally place such MAICs. (See Declaration of J. Kevin Gorospe, Chief of Medi-Cal Pharmacy Policy, California Department of Health Care Services, dated 10/29/09. Instead, California Medicaid typically paid using a lower of formula comparing FULs, which were lower than the California-specific MAICs, and EACs. (See Declaration of J. Kevin Gorospe). California Medicaid continues to pursue damages where EACs would have been lower than FULs on a given NDC if defendants had not published misleading pricing while concealing lower prevailing transaction pricing. (See Declaration of J. Kevin Gorospe). This Court did not find a lack of causation in this scenario and this Court’s rulings are completely consistent with Dr. Duggan’s methodology. Dr. Duggan exactly replicated Medicaid reimbursement formulas and essentially re-adjudicated approximately 70% of the reimbursements at issue after replacing the false pricing used with the previously concealed transaction pricing.⁴

Abbott also complains about Dr. Duggan’s sampling method. While it is true Dr. Duggan did not use a traditional random sample for the remaining small minority of Medicaid claims, a random sample was unnecessary given the extreme size of the “sample” which exceeded the universe to which the extrapolations were applied. Dr. Duggan analyzed voluminous actual claims-level data for millions of Medicaid claims. Dr. Duggan then painstakingly applied this actual Ery Medicaid claims data analysis in drawing appropriate economic extrapolations to the remaining minority of Ery Medicaid claims represented through summary-level data. In this less

⁴ “In this report I use data from different sources to determine the amount by which spending by the federal-state Medicaid program would have changed if alternative values had been used for Abbott products’ Average Wholesale Prices (AWPs), Wholesaler Acquisition Costs (WACs), and Direct Prices (DPs). For my analyses, I focus on the 43 NDCs listed in the Relator’s Complaint on behalf of the United States (hereinafter Complaint).” (See Expert Report of Dr. Duggan at p. 7).

common situation where extrapolation was necessary, Dr. Duggan always acted in a manner to underestimate, rather than overestimate, Medicaid claims “differences” (ie., overpayments or damages resulting from Abbott’s pricing conduct). Abbott ignores these “conservative” actions. Dr. Duggan’s data “sample” was not only sufficiently representative but was a majority of the whole and was carefully compared to the remaining data for reliability. (See Declaration of Dr. Duggan ¶¶ 17-19). If anything, Dr. Duggan’s work was overly thorough, as opposed to deficient or lacking. His support for extrapolating damages is strong and his techniques are common in the field.

Because Abbott purposefully restricted its own experts by prohibiting them from performing any competing calculations or statistical analysis whatsoever, Abbott has failed to demonstrate that Dr. Duggan’s method was not reliable. Abbott relies upon an economist to whom it denied access to the data, who is not as experienced in dealing with extremely voluminous datasets in the realm of healthcare economics, and whose primary opinion was that Dr. Duggan should have articulated more support for his approach to demonstrate its reasonableness. This type of vague, unsubstantiated critique hardly indicates Dr. Duggan’s analysis was unreliable.

APPLICABLE LAW

Expert Testimony

In determining the admissibility of expert testimony, the trial court must determine whether the expert is qualified and whether the expert’s testimony is sufficiently reliable and “relevant to the task at hand.” *Daubert*, 509 U.S. at 597. “The proponent need not prove to the judge that the testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable.” *Id.* at 130 (quoting *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998)). The critical inquiry is whether the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire*, 526 U.S. at 152; *Crowe v. Marchland*, 506 F.3d 13, 17 (1st Cir. 2007).

Although the district court's gate-keeping function is essential, "the [c]ourt must, however, keep in mind the Supreme Court's admonition that, '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" *In re Neurontin*, 612 F. Supp. 2d 116, 131 (D. Mass. 2009) citing *Daubert*, 509 U.S. at 596). Moreover, "[a]n economist's failure to consider certain data is not fatal to the admissibility if the expert sufficiently explains her choice of data for her analysis." *In re Pharmaceutical Industry AWP Litigation*, 491 F. Supp. 2d 20, 86 (D. Mass. 2007). In this case, Dr. Duggan's analysis displays the intellectual rigor of economists outside of the courtroom and Abbott's alleged flaws in Dr. Duggan's analysis go "to the weight, not the admissibility of the testimony." *Id.*

The Measure of and Burden of Proof for Damages

Ven-a-Care has asserted two alternate damage theories in this case. The first seeks the entirety of the reimbursements paid to the customers of Abbott.⁵ The second seeks the difference between what was actually paid and what would have been paid had Abbott not reported inflated published prices creating mega-spreads while concealing the general transaction prices. Abbott's motion is solely directed at the second, more conservative theory.

FCA Damages

The United States may measure its damages by the amount that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.

United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943); *United States v. Woodbury*, 359 F.2d

⁵ The FCA attaches liability to the claim for payment. Once the claims were submitted to the government based on false pretenses, Abbott's customers had no right to receive payments for those services. *United States ex rel. Anti-Discrimination Center of Metro New York v. Westchester County*, 2009 WL 1108517 (S.D.N.Y. April 24, 2009); *U.S. v. Mackby*, 338 F.3d 1013 (9th Cir. 2003). No offset to the defendant is required. Congress specifically rejected a "no harm, no foul" argument: "such claim[] may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program...." S. Rep. No. 99-345, at 9, reprinted in 1986 U.S.C.C.A.N. 5266, 5275. This approach is directly supported by the deterrent nature of the FCA. Courts are accordingly guided by the principle that the United States' damages should be liberally measured to effectuate the remedial purposes of the Act.

370, 379 (9th Cir. 1966); *United States v. Ekelman & Assocs.*, 532 F.2d 545, 550 (6th Cir.1976); *United States v. Killough*, 848 F.2d 1523, 1532 (11th Cir. 1988).

While the government must prove damages beyond "speculation and guesswork," it need not do so to a mathematical precision. *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 263-264 (1946); *United States v. Killough*, 848 F.2d 1523, 1531 (11th Cir. 1988). In cases where a defendant's bad acts have made calculation of damages difficult, as Abbott's conduct has done in this case, the law eases the standards for damage measurement. *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931).

Extrapolation in Calculating Damages

Dr. Duggan performed a detailed review of a sizeable portion of the claims, then extrapolated to some of the other claims after confirming that the populations were comparable. This is an acceptable method. *United States ex rel. Loughren v. Unumprovident Corp.*, 604 F. Supp. 2d 259, 261 (D. Mass 2009). *See* US Common Reply Memorandum, Dkt. 6519, pp. 18-20.

A corollary point is that the submission of a claim does not need to be established by the actual claim. *United States ex rel. El-Amin v. George Washington University*, 522 F. Supp. 2d 135, 141-142 (D.D.C. 2007) ("nothing in the language of the FCA requires the actual claim form" to be presented to the factfinder.") It is not necessary "to produce evidence of every single claim submitted to the Government" as long as there is "sufficient evidence of claim submission in general." *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F.Supp. 2d 153, 161 (D.D.C. 2008); *United States ex rel. Magid v. Wilderman*, 2004 WL 945153 (E.D. Pa. 2004). In addition, "as the Supreme Court has said, 'direct evidence of a fact is not required. Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *United States v. Williams*, 216 F.3d 1099, 1103 (D.C.Cir.2000) (quoting *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325 (1960)).

The failure to include all possible factors in a reasonable estimation of damages is not fatal. *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, 488 F. Supp. 2d 719, 732 (N.D. Ill.

2007) (expert testimony was admissible even where data was missing and expert may have failed to account for all variables)(citations omitted).

FACTS

Dr. Duggan calculated an appropriate and conservative estimate of the difference between 1) what Medicaid programs reimbursed pharmacies for the Ery Abbott drugs, and 2) what Medicaid programs would have reimbursed had Abbott not concealed actual prices and instead published false, inflated prices.

Steps of Dr. Duggan's economic analysis:

(1) Use of Abbott's Concealed Actual Transaction Prices

The starting point for Dr. Duggan's damage calculation was Abbott's actual transaction prices. He conservatively used the average prices paid by retail pharmacies. His calculations left out prompt pay discounts and miscellaneous earned rebates which were not as substantial and consistent as other offsets. In addition with respect to calculating AWP, Dr. Duggan bumped up the average calculated prices by 25 percent in recognition of Abbott's admitted awareness that AWP was derived by adding such a 25% markup to its published wholesale cost for respective Ery drugs. This decision in the determination of "but-for" prices, in turn, causes the claim-by-claim readjudication to be very conservative. Accordingly, subsequent extrapolations from the claim-by-claim readjudication to the remaining minority of claims are grounded in an effort to insure reliability and, if anything, minimize over-estimation of damages.

(2) Use of Comprehensive Medicaid Claims Data along with Information About the Reimbursement Methods used by Medicaid.

Dr. Duggan used multiple, often overlapping, sources of state claims data which equipped Dr. Duggan with one or more sources of claims data for every state, NDC and quarter for which he calculated damages, all of which he was able to substantiate as reliable. A detailed discussion of the Medicaid data utilized by Dr. Duggan is set forth in his report and declaration. *See* Expert

Report of Dr. Duggan at pp. 26, 41, 46, 53, 58, 61, 65, 72, 76, 79, 83, 86, 88; see also Declaration of Dr. Duggan ¶¶ 12-16). A brief description follows.

Medicaid Data

For the state Medicaid analysis, Dr. Duggan used claims data from 48 states (excluding Arizona, Ohio, and D.C.). Some data was produced by approximately 30 states in connection with this litigation (“State-produced” data), and the remainder was collected by CMS from the states in the ordinary course of operating the Medicaid program. The data collected by CMS is known as Medicaid Statistical Information System (“MSIS”) data and is *claims-level* data. From the MSIS data, CMS derives *claims-level* State Medicaid Research Files (“SMRF”) data, known most recently as the Medicaid Analytic Extract (“MAX”) data, and such was maintained by CMS as produced in this case. CMS also collects and maintains aggregate State Drug Utilization Data (“SDUD”) data which was produced in this case.

Medicaid Reimbursement Methodologies

The United States retained an experienced consulting expert, Myers and Stauffer, to provide support to Dr. Duggan. At Dr. Duggan’s direction, Myers & Stauffer compiled information as to each state’s reimbursement methodology throughout the time period at issue. HC Ex. 24.

(3) Re-Adjudication of Millions of Individual Claims

The core of Dr. Duggan’s work was to re-process the claims using the alternative Abbott prices, and then calculate the difference (i.e. damages) between those results and what was actually paid. (See Expert Report of Dr. Duggan at pp. 29 and 31). Dr. Duggan calculated damages by individually re-adjudicating 5.357 million claims under the applicable state reimbursement algorithm using the state-produced claims data. (See Expert Report of Dr. Duggan at p. 89). These claims and damages formed the basis of Dr. Duggan’s Medicaid sample. The calculations conducted on this extremely voluminous sample constituted the large majority of Ery Medicaid claims nationwide. These calculations respected ceiling prices such as state Maximum Allowable Costs (“MACs”) or Federal Upper Limits (“FULs”). Notably, Dr.

Duggan only calculated differences in situation where these ceiling prices would not have been the basis for reimbursement because the concealed Ery transaction prices, if published, would have resulted in lower reimbursement. (See Declaration of Dr. Duggan ¶¶29 - ¶30). In those instances, Estimated Acquisition Costs (“EACs”) would have been below the ceiling price level as intended by the plain meaning of the MAC and FUL terms. (See Declaration of Dr. Duggan ¶¶26-27; 29-33). This type of approach is familiar to and has been utilized by this Court. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F.Supp.2d 20, 6-21-2007 (D. Mass. 2007).

(4) Extrapolation Calculations for the Minority of Claims at issue

Dr. Duggan examined *all of the data* (state-produced, SMRF/MAX, and SDUD) and performed numerous analyses to substantiate that the claims in the multi-million claim sample population were a reliable basis for extrapolations. Dr. Duggan then scrupulously noted differences in the populations and either declined to extrapolate or extrapolated only after making suitable adjustments to scale the extrapolation down (and never up). *See, e.g.*, See Declaration of Dr. Duggan ¶¶ 49 - 66. Dr. Duggan’s followed specific steps in estimating damages caused to the United States arising from the other claims. He analyzed the damage calculations resulting from the individual re-adjudication of well over five (5) million claims. Utilizing accepted techniques, then Dr. Duggan was able to draw appropriate extrapolations to the remaining minority of claims which were analyzed, but not individually re-processed.

Intra-state Medicaid Extrapolation

Dr. Duggan only needed to perform limited intra-state extrapolations for the 15 states with heavy Medicaid drug utilization because the state-produced claims data was extensive. Where the state-produced claims data did not cover substantially each and every claim quarter or year at issue, Dr. Duggan did make limited and appropriate use of additional actual Medicaid claims data. (See Expert Report of Dr. Duggan at pp. 21-89 and Tables 13-27). To do this, Dr. Duggan used the SMRF/MAX and SDUD data to calculate damages in those time periods. The

nature of these intra-state extrapolations was spelled out carefully for each state in Dr. Duggan's report through a separate, detailed sub-section for each state. *Id.* Because he proudly utilized such a comprehensive and accepted approach, Dr. Duggan provided these extremely detailed descriptions so his analysis could be easily tested and replicated. However, these explanations are too lengthy to reproduce or discuss in detail in this brief.

In total, for 68.5% of the 7.825 million claims for the 15 core states, Dr. Duggan used state-produced claims-level Medicaid data. He only used SMRF/MAX/MSIS claims-level data for 20.9% of the 15 core states' Medicaid claims and he only used aggregate SDUD data for the remaining 10.6 % of those states' claims. (See Expert Report of Dr. Duggan pp. 21 – 25 and Tables 11, 12A-12C, and 28; see also Declaration of Dr. Duggan ¶¶ 55-58.)

In addition to all of the foregoing analysis, Dr. Duggan also double-checked his extrapolations through various means, including applying his replication method to periods for which he actually had claims level data, and comparing the test extrapolation figure to his actual calculation for that time period. (See Declaration of Dr. Duggan ¶ 58.)

Inter-state Medicaid Extrapolation

After individually re-processing millions of Medicaid claims, Dr. Duggan determined if he could perform an accurate, reliable estimate through extrapolation of the damages caused by Abbott's inflated prices in states where he had not individually re-adjudicated each of the claims. Again, this accounts for a minority of the Medicaid claims at issue. As usual, Dr. Duggan was extremely thorough and performed numerous analyses to substantiate that the claims in his sample population were a reliable basis for extrapolations. His methodology is described in detail in his expert report. (See Expert Report of Dr. Duggan at pp. 39, 42, 45, 47-51, 54-59, 61-63, 66-67, 70-71, 73-74, 76-81, 84, and 87; see also Declaration of Dr. Duggan ¶¶ 59-66).

In sum, Dr. Duggan's special precautions to substantiate that the populations were similar and that his extrapolations were reliable included numerous factors. He noted 1) all of the states reimburse for the same Abbott Complaint drugs, 2) all of the states are subject to the same federal regulations, 3) all of the states use published prices when adjudicating claims, 4) all of the

states in the two groups of states have a “lower of” methodology, 5) the fraud ratio similarity across the 15 states- despite their different adjudication methodologies – is striking, 6) the relative prevalence of the use of AWP, WAC, DP, U&C was similar , including that the vast majority of states used AWP, 7) the fraction of states in the two groups that use the WAC is similar, and 8) the reimbursement scaling factors for the prices are on average similar between the two groups.

Again, Dr. Duggan’s approach was conservative in underestimating damages because he calculated the average paid-per-claim in the 15 states as compared to the 34 remaining smaller states and saw those states paid similarly or slightly more on a per-claim basis for the Erys than the 15 states. (See Expert Report of Dr. Duggan at pp. 88 and 89-92; see also Duggan dep. trans. pp. 190:19 – 194:7; see also ¶¶ 54, 64-66). Dr. Duggan concluded therefore that use of the 15 states’ data would be reasonable, albeit conservative, within the standards of his profession, and applied the fraud ratios found in the millions of actual claims to extrapolate damages separately for each NDC-QTR. Id.; see also Duggan dep. trans. pp. 101:1 – 102:13.

The “extrapolation damages” were directly based on the SMRF/MAX and SDUD data, all of which Dr. Duggan carefully reviewed and compared for completeness and quality.⁶ In general, Dr. Duggan used the SMRF/MAX data when it was available and used the SDUD data when it was not. (See Duggan Expert Rep. p.77 and Tables 26A and 26B).

ARGUMENT

Abbott is Responsible for Damages When Their Prices Would Lower Reimbursement

Abbott claims that it is not liable if the payment for a drug was based on any price other than a published compendia price, or on a formula that did not exactly match the state’s reimbursement methodology. This is not a basis to exclude the testimony of Dr. Duggan. The United States and Ven-a-Care thoroughly addressed this issue in their summary judgment

⁶ Dr. Duggan reviewed the data in this step using the same approach as he had done for the intra-state calculations. Thus, he reviewed each claim to confirm its reliability, excluding for example all claims that showed a paid amount of zero or which had a strictly positive third party payment amount. (See Declaration of Dr. Duggan ¶ 65).

response memorandum in the intervened Abbott case, Docket 6519, pp. 14-18, and in this instant Response by Ven-a-Care. The evidence is overwhelming that by fraudulently inflating its prices, Abbott catapulted the Medicaid reimbursement upward; the failure of the reimbursement to reach, what otherwise would have been its apex, because of Medicaid use of ceiling prices which acted to slightly counteract Abbott's fraud does not break that initial causal link.⁷ See *Mylan Labs*, 608 F. Supp. 2d at 147 (explaining why providers' entry of inflated usual-and-customary charges did not insulate defendants from liability because of a state's lower of methodology). To the contrary, the action of the Medicaid programs to effectively mitigate some damage simply evidences the efforts of Medicaid programs to desire lower drug reimbursement amounts. Dr. Duggan only calculated reimbursement differences in those situations where the lower Abbott prices would have created an estimated acquisition cost for drug ingredient reimbursement purposes which was lower than the applicable ceiling price, if any. Thus, Dr. Duggan's approach to evaluating damages was fully warranted and completely consistent with the rulings of this Court and FCA causation standards.

Non-Random Samples are Routinely Used in Litigation

Abbott suggests at page 14 of its Memo that the *Reference Manual on Scientific Evidence* mandates the use of random samples in all instances. That is incorrect. Abbott does not point the Court to page 244 of the same manual which notes that non-probability samples are often used and found to be reliable. Even one of Abbott's experts concedes that samples need not be random. (See Hughes dep. trans. at p. 380:0 to 383:4 and Hughes Deposition Transcript Excerpt marked as Exhibit "1"). The *Reference Manual* does caution that the expert should be prepared to justify the method used to select the sample and that special precautions are required to reduce the likelihood of biased samples. The massive "samples" (which comprise over a super-majority of the claims) relied upon by Dr. Duggan in combination with detailed analysis of all of data satisfies this caveat. The *Reference Manual* is remarking upon the typical sample of a few dozen

⁷ In *Mylan*, 608 F. Supp. 2d at 147, this Court stated that "if the true U & C were lower than a true WAC, the defendants would only be liable for the amount of reimbursement in excess of the true WAC." As to MACs and FULs, the government is faced with the flip-side of that situation.

or few hundred units, not 7.825 million actual claims re-adjudicated/processed by Dr. Duggan. Dr. Duggan's methodology is vastly superior to even the non-probability samples cited approvingly in the *Reference Manual*.

Abbott presents no counter analysis other than biased, unrepresentative anomalies

Abbott asks this Court to exclude testimony of Dr. Duggan based upon its own cherry-picked, isolated, biased examples. Abbott's observations are misleading. For instance, the "Nebraska" issue results in an extrapolation which, even in Abbott's view, only results in a whopping \$20 more being calculated in damages than allegedly should have been.

Utilization				Original Pricing		But-for Pricing		Reimbursement Amounts Per Claim					Under (Over) Extrapolation	
State	Scripts	Units	Dollars	AWP	WAC	MAC	WAC	AWP	Dispensing Fee	Average Original	But-for Claim-by-Claim	But-for Extrapolated	Per Script	Aggregate
MO	324	10,912	2,634	0.1364	0.1091		0.0556	0.0695	4.09	8.13	6.19	6.44	0.26	83.28
NE	14	642	97	0.1364	0.1091	0.0650	0.0556	0.0695	4.66	6.90	6.90	5.47	(1.43)	(20.01)

While on the other hand, Abbott's own Missouri example actually results in Dr. Duggan's extrapolation underestimating damages by approximately \$80. *Id.* Again, proof that Dr. Duggan's extrapolations were accurate and, if anything, conservative. In total all of the examples presented by Abbott amount to only an alleged over-estimation or an incorrect extrapolation in the amount of a mere \$170. *Id.* There is not a misplaced decimal in that figure. It really is only one-hundred and seventy dollars of alleged impact. This is hardly a rate of error (in the context of tens of millions of dollars of calculated overpayments resulting from Abbott's pricing scheme) which indicates Dr. Duggan's work is unreliable. While Abbott is free to try to use these silly examples on cross-examination of Dr. Duggan, they certainly do not form a basis to exclude his testimony. None of Abbott's examples effectively undermine Dr. Duggan because they do not provide the necessary showing that Dr. Duggan's work is unreliable. Abbott disregarded virtually the entire population of data and did not quantify any actual reliability problem because none actually exists.

Abbott's experts' opinions do not support the relief requested

Abbott cites to copies of the reports of Stephen J. Young and James W. Hughes in support of their Motion and incorporated those reports in its Statement of Facts.

Stephen Young is a CPA with a Bachelor's degree in accounting who agrees that his accounting expertise was not brought to bear on this case. (See Young dep. trans. at pp. 136:16-22, 137:16 to 137:11, 140:17 -22, 214:19 to 215:7). Yet, only this non-economist, Young, reviewed the data, and only for the purpose of replicating Dr. Duggan's calculations. Based on what he did review he found only modest differences, all of which were either immaterial or corrected. Although he has been paid over \$1.5 million by Abbott, he did not perform any quantitative or statistical analysis of Dr. Duggan's work: "My opinions in this matter are not related to opining upon the statistical methodologies or basis [of Dr. Duggan's work']. *Id.* at 566:6-9. Indeed, he has no such expertise other than some undergraduate course-work in statistics and economics. *Id.* at 136:16-22, 137:16 to 137:11, 140:17 -22, 214:19 to 215:7. The only expertise he brought to bear on the case was his view of the standard manner in which overpayments were calculated in the health care arena: "My opinions are based on what the standards are in the industry based on what I've seen for individuals to calculate to sustain a position that there's been overpayments." *Id.* at 566:10-17; 565:9-11 ("I do not believe that the opinions in my report are based on the statistical analysis that [Dr. Duggan] has performed"); *Id.* at 562:19-21 ("the standard that I am applying is what I have seen historically necessary to support an overpayment of a claim to a provider"); *Id.* at 563:17-19 ("my role was not to get into the statistics or lack thereof associated with his analysis").

Dr. Hughes has a Ph.D. in economics and is a Professor at a liberal arts college. (See Hughes dep. trans. at 153:1-11). He has never performed any analysis of SMRF/MAX data, has minimal experience with individual Medicaid or Medicare claims data or SDUD data, never extrapolated damages in a Medicaid case, and never calculated J-code damages. *Id.* at 129:19-130:16, 134:2-20 and 145:2-15. Abbott counsel chose to prevent all data used by Dr. Duggan from reaching Dr. Hughes and did not allow him to perform a quantitative analysis of the work

performed by Dr. Duggan. *Id.* at 616:12-13. The primary thrust of Dr. Hughes' opinion was that Dr. Duggan should have more fully articulated the underlying basis for portions of his analysis. Dr. Hughes could articulate no objective standard by which he thought Dr. Duggan should be held – based upon economic principles or otherwise. *Id.* at 345:1-9 (“When you're doing data analysis, you want your data to be as accurate as possible. That's the standard.”) Dr. Hughes' opinion was based upon his suspicion that there were factors that would have lowered Dr. Duggan's damages calculations, but Dr. Hughes did not consider factors that would have raised Dr. Duggan's damages calculations. Dr. Du approach considered both factors that would increase as well as decrease calculations. See Declaration of Dr. Duggan ¶ 54. At best, Dr. Hughes' opinions provide ammunition for Abbott to cross-examine Dr. Duggan at trial on its theories. No opinion offered by Dr. Hughes comes close to warranting exclusion of any or part of Dr. Duggan's opinions.

Dr. Duggan, an expert on the methodology he applied in this case, pointed to economic literature discussing this approach. Importantly, Abbott's two experts were not familiar with the econometric method used by Dr. Duggan and other economists. It is difficult, then, to fathom how they can critique this approach or its application in a way that is helpful to this Court or a jury.⁸

Abbott's cited cases are distinguishable

The cases cited by Abbott in this or the intervened case are not supportive of Abbott's argument and are inapplicable to the instant facts. In *United States ex rel. Whipple v. Rockwell Space Operations Co.*, 2002 WL 864246, at 12* (S.D. Tex. Apr. 3, 2002), the court rejected an extrapolation from a lay person and in *United States v. Skoknek*, 933 F. Supp. 1108, 1115-18 (D. Mass. 1996) no expert performed the statistical extrapolation – the investigative unit attempted the calculations.

⁸ Abbott's experts may also have helped to overcome their lack of experience had they been able to quantifiably prove using statistics or some econometric method that Dr. Duggan's approach would lead to wildly disparate results as was done in the *Unum* case. Abbott's experts (the ones designated to testify) have not performed any such analysis because they were forbidden from doing so by counsel.

While Abbott cites *U.S. ex rel. Loughren v. UnumProvident*, 604 F. Supp. 2d 259 (D. Mass. 2009) as does Ven-a-Care and the United States (in the intervened action), that decision expressly concluded that “extrapolation is a reasonable method for determining the number of false claims so long as the statistical methodology is appropriate.” 604 F. Supp. 2d at 261. This court rejected the expert’s statistical sampling methods only after finding that the expert’s methods lacked peer-review and that an authoritative text cited by the expert did not once actually mention his method of “cohort sampling.” *Id.* at 266. Also, in that case, the opposing expert convincingly demonstrated the unreliability of the method by actually performing unequivocal, competing calculations. Such is not the case here.

Abbott also cites *Albert v. Warner Lambert Co.* 604 F. Supp. 2d 101 (D. Mass. 2002) as a case where a court refused to allow the jury to hear expert damages calculation. In *Albert*, the court states that “the fatal flaw in the survey . . . is the size of the sample on which the results are based.” *Id.* at 106. Comparing *Albert* to this instant situation is like comparing apples to oranges. The sample in *Albert* was twenty Medicare-eligible nursing homes in two states used as the basis for the nationwide universe of nursing facilities without providing any justification for doing so. *Id.* at 106, n.7. This incredibly small sample is the polar opposite of Dr. Duggan’s effort to duplicate and re-process almost all of the national Medicaid claims. Dr. Duggan’s sample was almost as large as the whole. The sample in *Albert* was the reverse; it was simple a drop in the bucket.

Abbott reliance upon *Allgood v. General Motors Corp.*, 2006 WL 2669337 (S.D. Ind. Sept. 18, 2006) is likewise misplaced. In this case the court excluded expert testimony regarding PCB contamination because the expert could not provide a scientific explanation for choosing the samples that he did. *Id.* at *11. Dr. Duggan thoroughly described the basis for his choices and produced all of his work in native format so his work could be easily replicated and checked.

Collyer Insulated Wire Co., 94 F.Supp. 493 (D.R.I. 1950), also is readily distinguishable because the district court refused to allow government witnesses to testify as to damages only because the testimony amounted to “hardly more than speculations and guesses.” *Id.* at 499. As noted in detail above, the work of Dr. Duggan and his use of methodologies accepted in his field of healthcare economics can hardly be described as “speculations” or “guesses.”

CONCLUSION

Abbott’s motion *in limine* seeks to confuse the record regarding Dr. Duggan’s actual analysis and methods. When the real work of Dr. Duggan is understood and those actual techniques are shown to be extremely thorough and well-accepted in the field of economics, then the reasons for Abbott’s effort at misdirection is better understood. Abbott desperately wants to avoid the jury considering the harm its pricing misconduct has caused, but this Motion cannot succeed in that regard. Abbott’s Motion should be denied in full.

Respectfully Submitted,

November 2, 2009

For the relator,
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/s/

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ James J. Breen

Dated: November 2, 2009